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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,137	08/29/2001	Christopher M. Angelucci	8932-538	6603
51832	7590	10/04/2005		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER REIMERS, ANNETTE R	
			ART UNIT 3732	PAPER NUMBER
DATE MAILED: 10/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,137

Applicant(s)

ANGELUCCI ET AL.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005 and 12 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 22, 26 and 28-52 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-25, 27 and 53-68 is/are allowed.
- 6) ☒ Claim(s) 1-8, 13, 14 and 16-21 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

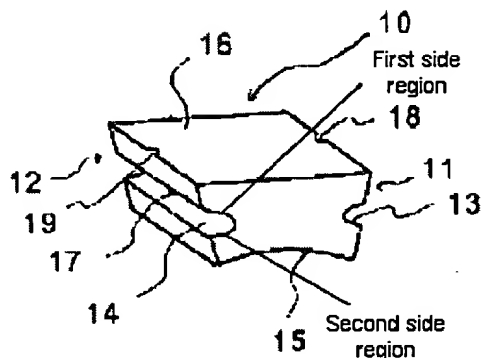
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2 and 16-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Yonenobu et al. (Reference "JP02000175943" cited on the IDS).

Yonenobu et al. disclose an implant comprising a body portion 10 having a length, a width and a depth (see figure 1). The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow portion 17. The body portion further has first and second ends that communicate with the hollow portion 18 (see figure 1B). The first and second ends comprise bone engaging portions 13, 14 having a single bone receiving channel that has a first depth relative to a first side region of the outer surface and a second depth relative to a second side region of the outer surface, the first and second depths having different measurements, the first and second side regions having substantially the same contour (see figure below). The perimeter of the outer surface of the implant is a geometric shape. The channel includes at least two angled faces and they have an arcuate shape. The implant further includes at least one hole or opening in communication with the outer surface and the inner surface. The

implant is fabricate from biocompatible metal or another such material (see paragraph 9).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-8, 13-14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonenobu (Reference JP02000175943" cited on the IDS).

Yonenobu et al. disclose the claimed invention except for the geometric shape being an ellipse, or a circle, or the implant being tubular shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of Yonenobu et al. having a geometric shape like an ellipse or circle or the implant having a tubular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or

configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implant site. In re Dailey and Eilers, 149 USPQ 47 (1966).

With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Yonenobu et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claims 7-8, 13-14 and 21, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Yonenobu et al. from bone allograft material, or demineralized cortical bone, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed June 13, 2005 have been fully considered but they are not persuasive. The vertebral arch spacer of Yonenobu has first and second side regions having substantially the same contour (see figure above).

Applicant's arguments with regard to claims 2-8, 13-14 and 16-21 do not overcome the rejections applied thereto, since applicant has not provide any convincing showing that these are nothing more than optimum or workable values, or more than

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one of numerous shapes or configurations, or known materials as asserted by the examiner. Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964)⁴ In re Kuhle, 188 USPQ 7 (CCPA 1975)) In re Davies, I 77 USPQ 38 1 (CCPA I 973). Mere arguments by counsel cannot take the place of evidence. In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 6 I 0 (CCPA 1948); et al.

Allowable Subject Matter

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-25, 27 and 53-68 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See prior PTO 892 mailed on 11/21/03 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR

AK



EDUARDO C. ROBERT
PRIMARY EXAMINER